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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,409      03/25/2004      Christian Viskov      03806.0579      5110

22852      7590      09/25/2006

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EXAMINER

KHARE, DEVESH

ART UNIT      PAPER NUMBER

1623

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/808,409

Applicant(s)

VISKOV ET AL.

Examiner

Devesh Khare

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-70 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121:

- I. Claims 39-41,44,45 drawn to a LMWH (low molecular weight heparin) and a composition having low or free of glycoserine, classified in classes 514, 424 and 536, subclass various.
- II. Claims 1-9, 42, 43, 46,47 and 62-65 drawn to a process for preparing LMWH of Group I and a method for determining the oligosaccharide content thereof, classified in class 536, subclasses various.
- III. Claims 10-38, 48-61 and 66-70, drawn to a method for determining/quantifying glycoserine content in heparin and a method of monitoring glycoserine in heparin, classified in 536 and 435, subclasses various.

The inventions are distinct, each from the other because of the following reasons:

Groups I to II are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for making the product can be practiced with another materially different product or (2) the product as claimed can be made in a materially different process of making that product (MPEP § 806.05(h)). In the instant case the the product as claimed can be made in a materially different process of making that product i.e. heparin fragments (LMWH) can be prepared in several ways such as by the treatment of standard heparin with nitrous acid in dimethoxyethane, see Lindahl et al. in IDS submitted on 11/21/2005 (EP 0014 184, page 3, 2<sup>nd</sup> para.).

Groups **I to III** are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for making the product can be practiced with another materially different product or (2) the product as claimed can be made in a materially different process of making that product (MPEP § 806.05(h)). In the instant case the process for making the product can be practiced with another materially different process i.e. a method for determining/quantifying glycoserine content in heparin and a method of monitoring glycoserine in heparin of Group I can be practiced with another materially different process such as in vitro amidolytic assays and structural identification by nuclear magnetic resonance and size exclusion chromatography, see Linhardt et al. in IDS submitted on 11/21/2005 (Seminars in Thrombosis and Hemostasis, vol.25, suppl.3, 1999, 5-16. especially page 10, under Analysis of heparin and LMWHS).

Inventions **II to III** are unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group II is drawn to a process for preparing LMWH of Group I and a method for determining the oligosaccharide content thereof, which is unrelated to the method for determining/quantifying glycoserine content in heparin and a method of monitoring glycoserine in heparin, of Group III.

Although the inventions are classified in the same class and sub-class, searching the three groups of inventions constitutes a burdensome search, as a thorough search comprises a search of foreign patents and non-patent literature as well as the appropriate U.S. patent classifications. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

It is noted that examination of the three independent and distinct inventions would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be considered for rejoinder. (MPEP § 821.04 and 821.04(b))

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

A telephone call was made to Lauren Stevens on 09/15/06, to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the


Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at

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(571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Devesh Khare, Ph.D.,J.D.  
Art Unit 1623  
September 15, 2006